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PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, December 2, 2015 at 9:00 a.m.**
PLACE:	**Buena Vista Conference Center, Buck Library, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	February 24, 2016

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Art Jankowski, VMD, Veterinary Representative
Philip Kim, M.D., Medical Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Stephen Ruggles, PA-C, PA Representative
Mark Hanna, Public Representative

MEMBERS ABSENT

Alex Zarow, R.Ph., Pharmacy Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Tejal Patel, PharmD
Hooshang Shanehsaz, R.Ph.
Ray Hancock
William Thompson
Ronald Levine
Jeff Goddess
Ganesh Balu, MD
L Gavin
Jeanne Chiquoine

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:02 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Ruggles, seconded by Mr. Von Goerres, to approve the minutes from the July 29, 2015 meeting. The motion was unanimously carried.

A motion was made by Mr. Von Goerres, seconded by Dr. Kremer., to approve the minutes from the September 23, 2015 meeting. The motion was unanimously carried.

PRESIDENT'S REPORT

No Report

UNFINISHED BUSINESS

Re-Review Consent Agreement – Ganesh Balu, MD – Ms. Kelly Deputy Attorney General of the committee explained the process of the consent agreement review. Dr. Ganesh Balu, Attorney Jeff Goddess and Ron Levine Partner of Post & Schell were present for the review. Mr. Levine thanked Ms. Kelly for her professionalism and assistance during the Consent Agreement process. Mr. Levine addressed the committee with argument regarding the requirement to report the Consent Agreement as a discipline to the National Practitioner Data Bank (NPDB). Mr. Levine provided the committee members with documentation he felt supported the request that this consent agreement is not required to be reported. Mr. Levine respectfully asked the committee on behalf of Dr. Ganesh Balu to strike paragraph #24 from the agreement and remove reporting this consent agreement to the NPDB. The committee re-reviewed the consent agreement as well as docuemnts presented to the committee on behalf of Dr. Ganesh Balu. A motion was made by Mr. Von Goerres and seconded by Dr. Kremer to to recommend the removal paragraph #24 from the consent agreement requiring reporting to the NPDB. The motion carried unanimously.

Non-Photo ID Cards – Ms. Kelly provided a draft of proposed amendments to Regulation 4.10 to include federal (military) ID's to 4.10.1.2 and language that would permit the obtaining of medications without ID in hospital discharge settings by adding an additional regulation 4.10.1.5. Dr. Kremer suggested language stating "immediately upon discharge" be added to 4.10.1.5. This addition will resolve the issues hospitals are experiencing however, this will not resolve the issues retail pharmacies experience with Non-Photo ID carriers. A motion to accept the proposed changes to regulation 4.10 and the addition of 4.10.1.5 with the changes discussed was made by Dr. Kim and seconded by Mr. Hanna. The motion Carried.

NEW BUSINESS

Review and Consideration of Hearing Officer Recommendation – Kelly Jamison, this agenda item was reviewed and determined by Ms. Kelly Deputy Attorney General of the committee that it is not required to be reviewed by the committee. This item was removed from the agenda.

DIRECTOR'S REPORT

Case/Diversion Review

Mr. Dryden stated that he has been completing practitioner inspections over the past couple of months. Mr. Dryden completed several Veterinary practitioner inspections that resulted positive results. He made a few recommendations for improvements within the facilities and overall the inspections have been going well.

Mr. Dryden attended the National Association of States Controlled Substance Authority (NASCSA) meeting in November. Presentation given by the Drug Enforcement Agency (DEA) and the Food and Drug Administration (FDA) were very informative. One of the hot issues discussed included designer drugs and their impact on the public.

Mr. Dryden made the committee aware of Division of Professional Regulation staffing changes. The current team is down my two staff members. Interviews were completed and those two positions have been filled effective December 2, 2015. Both candidates are from within the Division and should ramp up in their roles quickly.

Mr. Dryden met with the Delaware State Police Troop #2 and the DEA Taskforce regarding the geo-mapping project currently under way. The discussions included processes for requesting information as well as the type of information that is needed to provide positive results.

Current Event Review

FDA Implements Authority to Destroy Drugs That Have Been Refused Entry Into the US

Food and Drug Administration (FDA) is implementing its authority to destroy a drug valued at $2,500 or less that has been refused entry into the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The agency has issued a final rule, "Administrative Destruction of Certain Drugs Refused Admission to the United States," that is effective October 15, 2015. This regulation is authorized by amendments made to the FD&C Act by the FDA Safety and Innovation Act, according to the Federal Register. Implementation of this authority will allow FDA to better protect the public health by providing an administrative process for the destruction of certain refused drugs. Further, FDA's administrative destruction authority will "better protect the integrity of the drug supply chain by providing a disincentive for the importation of drugs that are adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act (21 U.S.C. 355) (unapproved drugs) and reducing the likelihood of such drugs being refused admission and subsequently offered for re-importation."

HHS Plans to Increase Access to Naloxone and Medication-Assisted Treatment

In response to the increase in opioid overdose-related deaths, United States Health and Human Services (HHS) Secretary Sylvia M. Burwell announced the agency's plan to increase access to naloxone in rural communities and expand access to medication-assisted treatment (MAT). Burwell announced the plan at a conference including representatives from the 50 states and Washington, DC, that focused on preventing opioid overdose and opioid use disorder. HHS plans to expand access to MAT by revising the current regulations related to prescribing buprenorphine to treat opioid dependence. MAT combines the use of medication with counseling and behavioral therapies to treat substance use disorders. Current regulations limit the number of patients to which physicians can prescribe buprenorphine as part of MAT, and the "HHS revision to the regulation will be developed to provide a balance between expanding the supply of this important treatment, encouraging use of evidence-based MAT, and minimizing the risk of drug diversion." Further, HHS plans to expand access to naloxone, a drug that reverses an opioid overdose. The Office of Rural Health Policy in HHS' Health Resources and Services Administration is awarding approximately $1.8 million in grants to rural communities in 13 states in an effort to reduce opioid overdose and death. With this funding, the communities will be able to purchase naloxone, train health care providers and local emergency responders in the use of naloxone, and facilitate the referral of people with opioid use disorder to substance abuse centers.

FDA Investigates the Risks of Using Tramadol in Children Aged 17 Years or Younger

Food and Drug Administration (FDA) is investigating the use of the pain medicine tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Tramadol is not FDA-approved for use in children; however, data show it is being used "off-label" in the pediatric population.

DEA Reports Strong Turnout for 10th Prescription Drug Take-Back Day

Over 702,365 pounds of unneeded, unwanted, or expired prescription medications were properly disposed of as part of Drug Enforcement Administration's (DEA) National Prescription Drug Take-Back Day Initiative on Saturday, September 26, 2015. DEA and its law enforcement partners provided over 5,000 collection sites across the United States, DEA reports. This was the 10th Prescription Drug Take-Back Day since the events began in September 2010. To date, DEA has collected more than 5.5 million pounds of unwanted medication for safe and secure

disposal. FDA Investigates the Risks of Using Tramadol in Children Aged 17 Years or Younger.

USP Publishes Notice of Intent to Revise Chapter on Sterile Compounding Preparations
The Compounding Expert Committee of the United States Pharmacopeial Convention (USP) intends to propose revisions to General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations* to improve clarity and reflect stakeholder input. The revisions made to the General Chapter include reorganized sections, merging of microbial risk categories into two categories, removal of information on handling hazardous drugs and adding of cross-references to General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*, and introduction of new terminology, "in-use time."

White House Announces Plan to Address Opioid Abuse and Related Rise in Overdose Deaths
In response to the rise in deaths related to prescription opioid and heroin overdose, President Barack Obama has announced federal, state, local, and private sector efforts aimed to prevent and treat opioid addiction. As part of the plan, President Obama issued a memorandum directing federal departments and agencies to provide opioid prescribing training to federal health care providers who prescribe controlled substances as part of their federal responsibilities. Obama intends for these federal efforts to serve as a model for similar actions throughout the United States. In addition, agencies that provide or facilitate access to health benefits are directed to review and identify obstacles to medication-assisted treatment for opioid use disorders and develop a plan to address these obstacles. Further, state, local, and private sector entities have made a commitment to ensure that more health care providers complete opioid prescriber training and to double the number of health care providers registered with their state prescription monitoring program (PMP). Further, these state and local entities have committed to doubling the number of physicians certified to prescribe buprenorphine for opioid use disorder treatment and to doubling the number of providers who prescribe the opioid overdose reversal drug naloxone, according to the White House press release. NABP's PMP activities were also cited in the news release.
Currently, 30 states are actively sharing PMP data using NABP PMP InterConnect®, the secure communications exchange platform that facilitates the transmission of PMP data across state lines to authorized requestors while ensuring that each state's data-access rules are enforced. The program launched in July 2011, with more state PMPs participating each year since the launch. Maryland was the most recent state to go live and joined PMPs in Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wisconsin. PMP InterConnect is expected to see continued growth moving into 2016 as one state has signed a memorandum of understanding (MOU) to participate and five states and one jurisdiction have MOUs under review. By end of 2016, NABP anticipates a total of 13 more states and one jurisdiction to be connected to PMP InterConnect.

NABP Supports Increasing Compounding Safety With Qualified Person Credentialing Program
With the goal of increasing compounding safety, CriticalPoint, LLC, has launched the Qualified Persons Credentialing Program (QPCP) for pharmacists at entities practicing compounding under sections 503A and 503B of the Drug Quality and Security Act (DQSA), Title I – Compounding Quality Act. NABP strongly believes that these pharmacists should be able to demonstrate knowledge, design sound compounding methodology, and develop effective quality systems in order to supervise such operations. The Association is partnering with CriticalPoint to inform its member boards of pharmacy about the QPCP and how the program

may assist the boards in establishing a formal and standardized system for evaluating, educating, and credentialing qualified persons for both 503A and 503B entities.

DEA Reports Controlled Substance and Heroin Abuse Spike, Increasing Drug Threat
Overdose deaths, particularly from prescription drugs and heroin, have reached epidemic levels, stresses Drug Enforcement Administration (DEA) in the 2015 National Drug Threat Assessment Summary. The number of deaths resulting from controlled substance (CS) abuse has surpassed the number of deaths attributed to cocaine and heroin combined, indicates the report. Further, people who abuse opioid CS are initiating heroin use, contributing to an increased demand for heroin. Therefore, controlled prescription drugs and heroin are ranked by DEA as the most significant drug threats to the United States.

DEA "360 Strategy" Aims to Address Prescription Opioid Abuse, Heroin Use, and Drug Trafficking With Pilot Program in Pennsylvania
DEA will begin to implement a new comprehensive strategy to address prescription opioid abuse, heroin use, and related violent crime by launching a pilot program in Pittsburgh, PA. The "360 Strategy" seeks to break the cycle of drug trafficking, heroin and prescription drug abuse, and the violence that accompanies it, using a three-fold approach. DEA's three objectives are as follows:

1. offer leadership in law enforcement operations targeting drug trafficking organizations and violent gangs that supply drugs to local areas;
2. engage manufacturers, wholesalers, prescribers, and pharmacists to raise awareness of the heroin and prescription drug abuse epidemic and advocate for responsible prescribing practices throughout the medical community; and
3. provide communities with the tools necessary to fight the epidemic.

"The community outreach aspect of this program may be the most important to long-term success," said Gary Tuggle, DEA Special Agent in Charge for the Philadelphia Division, in the press release. The plan includes engaging different groups in the community to educate young people about the consequences of drug abuse and trafficking.

PMP Review
None

COMMITTEE REPORTS
Medical Examiner's Report
No report.
DEA Report
No report
Substance Abuse Report
No Report
Law Enforcement Report
Agent Raymond Hancock, Delaware State Police – Drug Diversion Unit and Sergeant William R. Thompson, Delaware State Police Troop 2 opened discussion with the committee regarding fields of information not available on the current Prescription Monitoring Program (PMP) reports. The field of concern is the prescription blank number. The scenario provided is: if prescription pads are stolen there is no avenue through the PMP to search for these stolen blanks. They currently have to go to retail pharmacies and request a date range of prescription copies from the provider to manually try to locate stolen prescription blanks. If this field could be added, a search in the PMP would result in more timely investigations and possible recovery of prescription blanks before they are fraudulently used. This would also prevent a prescription blank being utilized first by fax and then filled by hardcopy at a pharmacy. Resulting in a prescription blank being utilized to received 2 prescriptions from one blank. Investigations have shown this occurs as well. Mr. Dryden stated that some of the possible issues is can retail pharmacies and their current systems accommodate an additional field. He also stated that

he will contact other states to see if they are utilizing this information and how. Ms. Tejal Patel, R.Ph. stated that currently New York enters the prescription blank number into their PMP system.

The committee asked that "Prescription Blank Utilization Discussion" be added to the February 24, 2016 agenda for further discussion.

Regulatory Committee Report
No Report
Legislative Committee Report
No Report

INSPECTION REPORT
Ms. McCreary reported she has been conducting routine inspections as well as joint inspections with the DEA. Inspection of the new Opiate Treatment location in Harrington was approved and the Smyrna location inspection will be completed in the near future.

COMMITTEE CORRESPONDENCE
None

OTHER BUSINESS BEFORE THE BOARD
Ms. Mast reported that new processes will be in place in 2016 to allow for electronic documents to be reviewed by the committee via IPad. The final stages of set up are almost completed. This will save valuable paper resources going forward.

PUBLIC COMMENTS
None

EXECUTIVE SESSION
None

NEXT SCHEDULED MEETING
The next regular meeting will be held on February 24, 2016 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT
A motion was made by Mr. Von Goerres, seconded by Dr. Kremer, to adjourn the meeting at 9:58 am. The motion carried.

Respectfully submitted,

Mast

Christine Mast
Administrative Specialist III
Office of Controlled Substances